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K133646

Page 1 of 5

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510(K) SUMMARY

FOR

ADMIRE

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: May 5, 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **General Information**
   Importer/Distributor:
   Siemens Medical Solutions USA, Inc.
   51 Valley Stream Parkway
   Malvern, PA 19355

   Establishment Registration Number:
   2240869

   Manufacturing Site:
   SIEMENS AG, MEDICAL SOLUTIONS
   Siemensstrasse 1
   91301 Forchheim, GERMANY

   Establishment Registration Number:
   3004977335

2. **Contact Person:**
   Mrs. Kimberly Mangum
   Technical Specialist, Regulatory Affairs Submissions
   Siemens Medical Solutions, Inc. USA
   51 Valley Stream Parkway D02
   Malvern, PA 19355-1406
   Phone: (610) 448-1772 Fax: (610) 448-1778
   Email: kimberly.mangum@siemens.com

3. **Device Name and Classification**

Product Name:	ADMIRE
Propriety Trade Name:	ADMIRE
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750

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Device Class: Class II
Product Code: 90JAK

Legally Marketed Predicate Devices
Trade Name: SAFIRE
510(k)#: K103424
Clearance Date: November 22, 2011
Classification Name: System, X-Ray, Tomography, Computed
Classification Panel: Radiology
Classification Regulation: 21 CFR § 892.1750
Device Class: II
Product Code: 90 JAK

4. **Substantial Equivalence:**
Siemens ADMIRE is substantially equivalent to the following medical devices in commercial distribution:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
SAFIRE	K103424	November 22. 2011

5. **Device Description:**
Siemens ADMIRE is an extension of the previously cleared Sinogram Affirmed Iterative Reconstruction (SAFIRE) reconstruction algorithm. ADMIRE is a software option for CT operating systems that provides an improved image quality or reciprocally can allow the physician to acquire scans with reduced radiation dose without reduction of image quality compared to today's standard.

ADMIRE is designed to improved reconstructed image quality through the integration of additional processing steps in image reconstruction. These additional steps result in the following improvements in image quality:

- Higher pixel noise reduction
- A noise texture closer to filtered back projection (FBP)
- Improved resolution for high contrast edges

6. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**
ADMIRE reconstruction software do not have significant changes in the indications for use, materials, energy source, or technological characteristics when compared to the predicate device.

The additional/extended algorithm processing steps result in the following improvements in reconstructed image quality for ADMIRE in comparison to the predicate device SAFIRE:

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- Higher pixel noise reduction in thicker slices (for example 3mm and 5mm)
- Less outliers in the noise texture resulting in a noise texture closer to that of filtered back projection (FBP)
- Improved Resolution at High Contrast Edges compared to weighted filtered back projection (WFBP)

The intended use and fundamental scientific technology are similar to the predicate device; therefore Siemens believes that they are substantially equivalent to the predicate device.

7. Nonclinical Testing:

ADMIRE is designed to fulfill the requirements of following safety and performance standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
5-40	General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	08/20/2012	ISO
13-8	Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	08/20/2012	IEC
5-41	General	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems, edition 1.1	60601-1-4: 2000 Consol.Ed 1.1	09/08/2009	IEC
	General	Medical electrical equipment - Part 1-6: General requirements for basic safety and performance	60601-1-6	2006	IEC
12-218	Radiology	Digital Imaging and Communications in Medicine (DICOM)	PS 3.1 – 3.18 (2008)	2008	NEMA

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) and phantom testing were conducted for ADMIRE during product development. The modifications described in this Premarket Notification were supported with verification/validation testing.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission.

EMC/electrical safety was evaluated according to the IEC Standards. Siemens certify conformance to Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. All testing and validation has been completed.

Summary of Additional Testing

In addition to successful completion of verification and validation testing, additional bench testing was performed to substantiate performance claims and demonstrate substantial equivalence to the predicate device SAFIRE. Sample clinical images were also provided within the submission.

8. **Indications for Use:**

ADMIRE is a CT reconstruction software. The end user can choose to apply either ADMIRE or the weighted filter back-projection (WFBP) to the acquired raw data. Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of ADMIRE can help to reduce radiation dose while maintaining pixel noise, low contrast detectability and high contrast resolution. Phantom measurements showed that high contrast resolution and pixel noise are equivalent between full dose WFBP images and reduced dose ADMIRE images. Additionally, ADMIRE can reduce spiral artifacts by using iterations going back and forth between image space and raw data space.

ADMIRE at highest noise reduction strength for thin (0.6 mm) reconstruction slices in simulated body and head phantoms for low contrast objects with different contrasts.

Images reconstructed with ADMIRE are not intended to be evaluated with syngo Osteo CT or syngo Calcium Scoring.

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9. General Safety and Effectiveness Concerns:
The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. Conclusion as to Substantial Equivalence

In summary, Siemens is of the opinion that the ADMIRE does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 20, 2014

Siemens Medical Systems, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19301

Re: K133646
Trade/Device Name: ADMIRE
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 8, 2014
Received: May 13, 2014

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

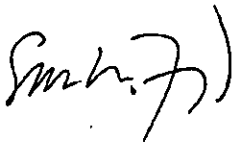
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133646

Device Name
ADMIRE

Indications for Use *(Describe)*

ADMIRE is a CT reconstruction software. The end user can choose to apply either ADMIRE or the weighted filter back-projection (WFBP) to the acquired raw data. Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of ADMIRE can help to reduce radiation dose while maintaining pixel noise, low contrast detectability and high contrast resolution. Phantom measurements showed that high contrast resolution and pixel noise are equivalent between full dose WFBP images and reduced dose ADMIRE images. Additionally, ADMIRE can reduce spiral artifacts by using iterations going back and forth between image space and raw data space.

Images reconstructed with ADMIRE are not intended to be evaluated with syngo Osteo CT or syngo Calcium Scoring.

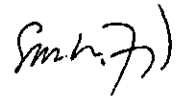
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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